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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,744	09/15/2003	Gin Wu	021218.0009US2	1532
34284	7590	11/08/2007		
Rutan & Tucker, LLP. Hani Z. Sayed 611 ANTON BLVD SUITE 1400 COSTA MESA, CA 92626			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 11/08/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/662,744

Applicant(s)

WU, GIN

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 23 is objected to because of the following informalities: the proximal and distal ends of the hub lack antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 14,15,17,18,22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by De Santis (US 5,560,373)

De Santis teaches a drill bit with a shaft (12), a first opening (end distal end of 13), a second opening (at the notch), a lumen (13), and a notch (46). Fig 7. The shaft is disposed in the hub (Fig 1).

2. Claims 14,15,17,19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw (US 5,261,818).

Shaw teaches a shaft (13) with a cutting surface (14), a lumen (18), with first (34) and second openings (22) and an open notch (26). Shaw also teaches a method of drilling through bone and injecting a substance through needle (Summary of the invention).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3767

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw.

Shaw teaches the drill as above, but does not teach the length of the drill or the use of a hypodermic needle to inject the substance. It is well known in the art to provide medications in a hypodermic needle/syringe system and to inject the substance in the body. The lumen of the drill bit would be capable of use with a hypodermic needle and one of ordinary skill in the art at the time the invention was made would have expected the device to be used with a hypodermic needle.

Regarding claim 16, Shaw discloses the entire length of the drill is 20-25 mm (0.78-.98 inches). The notches do not extend the entire length of the drill, and appear to extend roughly  $\frac{1}{4}$ -  $\frac{1}{3}$  the length of the shaft (about 0.19 inches). The examiner believes this is "about 0.1-0.125 inches." Additionally, the drill bit is intended for use in the mouth of a human and therefore must meet some dimensional limits in order to be functional.

### ***Response to Arguments***

5. Applicant's arguments filed 23 October 2007 have been fully considered but they are not persuasive. Applicant has argued that De Santis does not teach a drill for hard tissue or that the notch is longer than the tissue. In response to applicant's argument that the device is used for hard tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

prior art structure is capable of performing the intended use, then it meets the claim. Additionally, the device would function equally well if the notch was longer than the tissue.

6. Regarding Shaw, applicant has argued that debris does not enter the hole (34). This is not convincing because there is nothing blocking the hole to prevent lose debris and this is an intended use limitation. Regarding the length of the notch, this limitation does not provide a structural difference between the prior art and the claimed invention since "a thickness of the hard tissue" is not specific to any location on the hard tissue and is also an intended use limitation.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

